



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

Mail Code A-110

April 21, 1993

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OFFICE OF
THE ADMINISTRATIVE
LAW JUDGES

1993 APR 21 AM 10:40
EPA HEADQUARTERS
HEALTH, SAFETY & ENVIRONMENTAL
RECORDS SECTION

Subject: Dr. Robert Schattner, President
and Sporicidin International, Inc.
a/k/a Sporicidin Company,
Docket No. FIFRA-92-H-02

Dear Counselors:

Enclosed is a memorandum summarizing the Pre-hearing Conference held at EPA Headquarters at 10 a.m. on April 20, 1993. Please inform the ALJ within 10 days whether there are any corrections which should be made or omissions which should be supplied to the memorandum.

Sincerely yours,

Spencer T. Nissen
Administrative Law Judge (Mail Code A-110)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460
Telephone: 202-260-0040
Fax: 202-260-3720

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In the Matter of)
)
Dr. Robert Schattner, President) Docket No. FIFRA-92-H-02
and Sporidicin International,)
Inc., a/k/a Sporidicin Co.,)
)
Respondents)

1993 APR 21 AM 10:40

RECEIVED
EPA HEADQUARTERS
HEARING ROOM

PRE-HEARING CONFERENCE
ROOM 2409, EPA HEADQUARTERS
10:00 A.M., APRIL 20, 1993

ATTENDEES:

Marged G. Harris, Office of Enforcement, EPA
Michael J. Walker, Office of Enforcement, EPA
Mary McDonnell, Office of Compliance Monitoring, Office of
Prevention, Pesticides & Toxic Substances
Richard J. Leon, Baker & Hostetler, Sporidicin
Brooks Bowen, Sporidicin International

The Conference opened with a discussion of pending motions:

I. Sporidicin's Motion For Protective Order

The ALJ observed that he clearly had authority to issue a protective order and that he did not understand the mind set that every motion by the opposition had to be opposed. Ms. Harris represented that the question of whether the additional documents covered by Sporidicin's motion were CBI was under review by OGC. The ALJ stated that the documents covered by the motion had been received from Complainant with no indication that CBI status was claimed, but that since receipt of the motion his office and the Hearing Clerk's office had treated the documents as CBI. He

admonished Complainant to do the same unless and until OGC ruled otherwise.

II. Discovery

The ALJ expressed his concern that the less data EPA furnished as to the manner of conducting the tests at issue the more advantageous it was for the Agency. This is because Complainant could simply present the test reports, have the person or persons who conducted the tests testify that the tests were conducted in accordance with all appropriate criteria and Sporidicin, having no effective way of countering such evidence, would lose.^{1/} The ALJ observed that Complainant objected to furnishing all data on the testing.

With regard to specific motions:

A. Complainant's Motion To Reconsider the February 19 order requiring production of documents. This motion was denied.

B. Complainant's Motion to Find Compliance. The ALJ stated that EPA had not fully complied, but doubted that the matter was worth pursuing in that the parties should be devoting their time to hearing preparation rather than appeals of discovery orders.

Ms. Harris repeated Complainant's contention that EPA had no idea of the precise documents Sporidicin was seeking and emphasized the burden the request was placing on the Agency. Mr. Bowen argued

^{1/} This is illustrated by Complainant's assertion, correct as far as it goes, that Sporidicin must rely on its own experts. If Sporidicin is to receive a fair hearing, however, it is essential that all data on the testing be made available.

that the documents were relevant and probative on the issue of the reliability of the AOAC test and minimized the burden of asking named persons whether documents within the description existed. The ALJ did not make a final ruling.

III. Motion To Strike Portions of Sporicidin's Pre-Hearing Exchange

A discussion ensued on the status of tests on samples of SCSS by independent laboratories and of Complainant's separate proceeding against Sporicidin for violations of the SSURO. The ALJ observed that he could not understand how shipping samples for testing could be a public health concern and that this was tantamount to requiring Complainant's approval of Sporicidin's defense. Ms. Harris stated that the Agency became aware of the violations by chance and that the seriousness of the violation related to Sporicidin's defiance of the SSURO.

With respect to specific proposed exhibits, the ALJ stated he saw no basis for admission of transcripts of expert testimony from the Metrex Research Corporation action, because counsel for Complainant would not be able to cross-examine such experts. Statements and opinions offered by experts will presumably be qualified as such. With respect to Sporicidin's proposed exhibits CC, B, C & D, E, F & G, N & O, the ALJ indicated that the objections appeared to be valid, but made no final rulings.

IV. Motion For Sporicidin To Cease Ex Parte Communications

The ALJ observed that he was not impressed by this motion as it did not appear to be valid. For example, a letter to the Administrator concerning duplicate regulation of SCSS and other sterilants by FDA and EPA was not necessarily related to the merits of the instant case. Moreover, because there are other glutaraldehyde sterilants on the market, the concerns expressed in Dr. Schattner's letter to Michael Wood, dated March 8, 1993, concerning selective prosecution raises an issue which also concerns the ALJ. Lastly, although the Administrator could theoretically direct the EAB to refer a particular matter to her for decision (or the EAB could, at its option, refer a particular matter to the Administrator), the likelihood of either event happening in the instant proceeding is so remote as to approach the vanishing point.^{2/} This motion was denied.

V. Hearing Date

Mr. Bowen stated that Sporicidin would not insist on the hearing being held in Rockville and that a hearing at EPA Headquarters was acceptable. Mr. Leon estimated that a hearing might require two or three weeks unless the issues could be substantially narrowed. He indicated that Sporicidin had only recently acquired certain scientific evidence and that the matter

^{2/} It is, of course, recognized that the prohibition against ex parte communications is directed to the appearance of improper contacts or influence as well as the reality thereof.

of further discovery by means of interrogatories had been discussed with counsel for Complainant.

Ms. Harris stated that Complainant could put on its case in one day and urged that an early hearing date be set. She emphasized that pre-hearing exchanges had been submitted in July of 1992, and that Sporicidin had not submitted summaries of witness testimony. The ALJ declared that Sporicidin would be allowed every opportunity to develop its defense.

The ALJ agreed to initiate a telecon on May 7, 1993, at 10:00 a.m. at which time counsel would report the status of possible settlement, and, failing settlement, the result of discussions focused on narrowing the issues and additional discovery required by Sporicidin. Sporicidin agreed to file qualification statements of expert witnesses, to the extent identified, by that date.

Conference adjourned at 11:30 a.m.

Dated this 21st day of April 1993



Spencer T. Nissen
Administrative Law Judge

CERTIFICATE OF SERVICE

I do hereby certify that the foregoing Pre-Hearing Conference Memorandum was filed in re Dr. Robert Schattner, President and Sporidicin International, Inc. a/k/a Sporidicin Company; Docket No. FIFRA-92-H-02 and a copy of the same was mailed to the following:

(Inter Office)

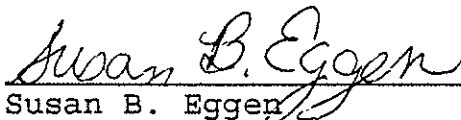
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Susan B. Eggen
Office of the Hearing Clerk
U. S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dated: April 21, 1993